IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ROANOKE DIVISION

DEIRDRE WILLIAMSON JAIN, and EMILY RUTH WILLIAMSON, *Individually, and as Co-Administrators of the Estate of Joseph Seth Williamson, II, Deceased,*	)	
Plaintiffs,	)	**Civil Action No.: 7:13cv00551**
v.	)	
ABBOTT LABORATORIES, INC., et al.,	)	**By: Hon. Michael F. Urbanski United States District Judge**
Defendants.	)	

MEMORANDUM OPINION

This is a products liability action brought by Deirdre Jain and Emily Williamson (collectively "Plaintiffs"), against Abbott Laboratories, Inc., Abbott Laboratories and Hospira, Inc. (collectively "Defendants"), concerning the alleged misprogramming of a patient-controlled analgesia pump. Plaintiffs allege that Defendants negligently failed to provide adequate instructions for manually programming the drug concentration into the pump, failed to warn of the defect and breached express and implied warranties rendering the pump unreasonably dangerous and resulting in the death of Joseph Seth Williamson, II ("Williamson").

Before the court are several motions. In two pending motions in limine, Defendants seek to exclude the expert testimony of Drs. Shelly Collins and Kenneth Laughery (Dkt. Nos. 73 and 71). Defendants' motion to exclude the expert testimony of Dr. Arden (Dkt. No. 49) is the subject of a report and recommendation issued by the magistrate judge on October 8, 2014 (Dkt. No. 60). Defendants' objection to that report is currently pending before the court (Dkt. No. 67). Defendants also move for summary judgment (Dkt. No. 69).

The issues have been fully briefed, and the court heard oral argument on November 25, 2014. For the reasons set forth below, the motions to exclude Dr. Shelly Collins (Dkt. No. 73) and Dr. Kenneth Laughery (Dkt. No. 71) are **GRANTED in part** and **DENIED in part**. Defendants' objection to the magistrate judge's report and recommendation as to Dr. Jonathan Arden (Dkt. No. 67) is **OVERRULED** and the report and recommendation (Dkt. No. 60) is **ADOPTED** in its entirety. Finally, because genuine issues of material fact exist in this case, the motion for summary judgment (Dkt. No. 69) is **DENIED**.

I.

On October 6, 2011, Williamson underwent hernia repair surgery at Montgomery Regional Hospital ("MRH") in Blacksburg, Virginia. In order to manage post-operative pain, Williamson's doctor prescribed him Dilaudid, a narcotic pain medication, to be administered via a patient-controlled analgesia pump. Williamson's doctor prescribed a continuous dose of Dilaudid at 0.5 mg per hour, with a 0.2 mg patient-administered dose, a 20-minute lockout for patient-administered doses, and a 3 mg, 4-hour limit. The pump used at MRH was the Defendants' Hospira LifeCare PCA® 3 Infusion System ("PCA 3"). The PCA 3 uses either a pre-filled or custom vial also manufactured by Defendants to administer medication, and it utilizes a scanner to read a bar code printed on the vial. After scanning the barcode, the PCA 3 either recognizes the vial as a pre-filled vial of a particular medication or a custom vial requiring the user to provide more information about the medication.

At the time of Williamson's surgery, MRH used custom vials to administer Dilaudid. Thus, after inserting a vial of Dilaudid into the PCA 3, the user, usually a nurse, would have to program the concentration of the drug along with the dosage prescribed by the patient's physician into the PCA 3. The concentration of Dilaudid in the custom vials at MRH was 1.0 mg/ml. Williamson's primary nurse asked another on-duty nurse to assist her with the programming of the PCA 3 for

Williamson. While programming the PCA 3, the nurses entered ".2" for the drug concentration rather than "1.0". Plaintiffs contend that the instructions and warnings on the PCA 3 pump were inadequate and misleading resulting in the programming error. Significantly, Plaintiffs point to the fact that a screen on the PCA 3 pump states "CONFIRM CONCENTRATION TO PHYSICIAN RX." Plaintiffs allege that this screen misled the nurses into manually programming the wrong concentration of Dilaudid into the pump, causing Williamson to receive a much a higher dose of Dilaudid than that prescribed by his physician. At 1:10 a.m. on October 7, 2011, Williamson's nurse found him unresponsive, and he was pronounced dead shortly thereafter. Plaintiffs contend that the overdose of Dilaudid caused Williamson's death.

II.

Plaintiffs have identified Drs. Jonathan Arden, Shelly Collins, and Kenneth Laughery as experts to testify at trial. Defendants have moved to exclude all three expert witnesses and also move for summary judgment. The court will address each of these motions in turn.

A. Objection to Report and Recommendation Regarding Dr. Arden (Dkt. No. 67).

Plaintiffs seek to call Dr. Arden as a rebuttal expert witness on the cause of Williamson's death. Defendants have objected, claiming the identification of Dr. Arden was untimely. Finding no surprise or prejudice to the Defendants, the magistrate judge recommended that the motion to exclude Dr. Arden be denied. After conducting a de novo review of Defendants' motion to exclude Dr. Arden, the court agrees with the magistrate judge's recommendation that the untimely disclosure of Dr. Arden was harmless. Plaintiffs disclosed Dr. Arden in sufficient time to allow his deposition to be taken before the close of discovery. Because Defendants had the opportunity to depose Dr. Arden before the close of discovery, Dr. Arden's testimony is relevant to an important issue in this case, and finding no surprise or prejudice in allowing Dr. Arden to testify as a rebuttal witness, the court finds that the untimely disclosure of Dr. Arden was harmless pursuant to Federal Rule of Civil

Procedure 37(c)(1). See Hoyle v. Freightliner, LLC, 650 F.3d 321, 329 (4th Cir. 2011). Therefore, Defendants' objection (Dkt. No. 67) is **OVERRULED**, the report and recommendation (Dkt. No. 60) is **ADOPTED** in its entirety, and Defendants' motion to exclude Dr. Arden (Dkt. No. 49) is **DENIED**.

B. Daubert Motions Regarding Expert Witnesses Drs. Collins and Laughery (Dkt Nos. 73 and 71).

When expert opinion evidence is offered, the court is obligated to serve as a gatekeeper to determine whether an expert witness is qualified and whether an expert opinion is grounded in objective underlying scientific methodology, as opposed to mere speculation or conjecture. Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579, 589–590, 595 (1993); Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141–142 (1991). The applicable rule governing admissibility of expert testimony is Federal Rule of Evidence 702, which provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702; see also Advisory Committee Notes to Rule 702, 2000 Amendments ("A review of the case law after Daubert shows that the rejection of expert testimony is the exception rather than the rule.") The applicable rule governing the legitimacy of underlying bases of opinion testimony by experts is Federal Rule of Evidence 703, which provides in part:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted.

Fed. R. Evid. 703. In other words, expert testimony that can assist the trier of fact is to be admitted at trial where the witness is qualified and a preliminary assessment of his testimony finds "the reasoning or methodology underlying the [proffered] testimony is scientifically valid and . . . that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592-593.

In order to qualify as an expert, an individual must possess the requisite knowledge, skill, experience, training or education. Virginia Vermiculite, Ltd. v. W.R. Grace & Co.-Conn. & The Historic Green Springs, Inc., 98 F. Supp. 2d 729, 732 (W.D. Va. 2000). An expert need not "possess all five requisites—as long as he possesses one, he may be deemed an expert." Id. "Rule 702 was intended to liberalize the introduction of relevant expert evidence." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999); see also Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 799 (4th Cir. 1989) (recognizing that the test for exclusion of an expert is a strict one). As such, a court need not determine whether the experts' testimony is correct but should leave such conclusions to the jury after "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." Westberry, 178 F.3d at 261 (quoting Daubert, 509 U.S. at 596). However, courts must be mindful that experts have the potential to be misleading if their testimony is not reliable. Expert testimony with a greater potential to mislead than to aid the jury should be excluded. See Westberry, 178 F.3d at 261 (citing United States v. Dorsey, 45 F.3d 809, 815–16 (4th Cir. 1995)).

1.

Defendants ask the court to prevent Dr. Collins from "proffering any testimony on the adequacy of the instructions and warnings accompanying the PCA 3, how nurses would or did interpret them, and that any different warning would have prevented the misprogramming . . . of the PCA 3." Dkt. No. 74, at 10. Dr. Shelly Collins possesses the requisite knowledge, skill, experience,

training, and education to qualify as an expert in the field of clinical pharmacology in this case. She holds a Ph.D. in pharmacy and has more than twenty-eight years of clinical pharmacy experience. She spent the last eighteen years as Clinical Specialist/Clinical Coordinator at the Chesapeake Regional Medical Center where she was responsible for managing drug errors with pharmacists and technicians with areas of emphasis in medication safety and quality improvement. Dkt. No. 74-3. She has given numerous presentations in her field, including ones on protecting patients with sleep apnea,[1] and co-authored a text on pharmacology and nursing. Finally, Dr. Collins has had ample interactions with PCA pumps generally throughout her career, although not the one at issue in this case.

At oral argument, the court indicated that Dr. Collins ought not be permitted to testify that Williamson died as a result of an overdose of Dilaudid. As Dr. Collins is not a medical doctor, she is not qualified to testify as to the cause of Williamson's death. At the same time, however, Dr. Collins plainly is qualified to testify that Williamson received an overdose of Dilaudid and that the "overdose occurred due to the programming of the wrong concentration of Dilaudid into the PCA pump," Dkt. No. 74-1, as well as to testify consistent with the opinions set forth at paragraphs 2-10 of her June 27, 2014 report. Dkt. No. 74-1. As such, the motion in limine regarding Dr. Collins' testimony (Dkt. No. 73) is **GRANTED in part** and **DENIED in part**.

2.

Defendants also move to exclude Dr. Kenneth Laughery from testifying on the adequacy of the warnings and instructions on the PCA 3. Dr. Laughery holds a bachelor's degree in metallurgical engineering and master's and doctoral degrees in psychology. Dr. Laughery is a certified human factors engineering professional and past president of the National Human Factors and Ergonomics Society. He has taught graduate and undergraduate level courses in the field of human factors and

[1] Williamson suffered from sleep apnea, and this condition will be an issue in this case.

published articles on warnings, human factors and ergonomics. Despite Dr. Laughery's training, education, and skill, however, he has not seen the PCA 3 in person, seen it programmed, or even talked to someone who has programmed it. Laughery Dep., Dkt. No. 72-2, at 53:19-54:10, 162:4-9. Laughery has no experience in the design of medical devices or their warnings. Id. at 62:22-64:4. Laughery did not conduct any testing as to the particular warnings and labels on the PCA 3. Id. at 128:10-129:2. Moreover, a portion of Dr. Laughery's expert opinion appears to be based on a mistaken understanding of the PCA 3 and a prior PCA manufactured by Defendants. Compare Dkt. No. 72-1 at *8 with Dkt. No. 72-1 at 94:5-101:1, 119:14-20. Finally, Dr. Laughery consistently discounts testimony provided in this case in order to support his opinion. See Laughery Dep., Dkt. No. 72-2 at 149:5-153:2. It is the role of the jury, not expert witnesses, to make credibility determinations.

The gravamen of Dr. Laughery's opinion is that the warnings contained on the side of the pump and in the operator's manual were insufficient from a human factors perspective, and that the pump's on-screen instructions were misleading and lacked an adequate warning of the dangers of misprogramming the wrong drug concentration. For their part, Defendants have identified Alan Lipshultz, a professional engineer and certified safety professional, whose expert opinion disagrees with Dr. Laughery's. Moreover, Defendants themselves considered human factors issues when developing and evaluating the PCA 3. As the deposition of Ella Cozmi, Director of Human Factors Engineering for Hospira, Inc., makes clear, human factors engineering has played a role in the design of the PCA 3. As such, Dr. Laughery will be permitted to testify on the adequacy of the instructions and warnings associated with the PCA 3, to the extent those opinions are well grounded in his training, education and experience as well as recognized research and literature in the field of human factors engineering.

At the same time, Dr. Laughery is not qualified by anything other than conjecture to render an opinion as to causation in this case. He will not be permitted to opine that the instructions and warnings associated with the PCA 3 caused the nurses to misprogram the PCA 3 resulting in the overdose and death of Williamson. By the same token, in his deposition, Dr. Laughery testified that he believed that certain of the nurses' testimony reflected their knowledge obtained in hindsight rather than what they knew at the time of Williamson's death. Dr. Laughery's speculation in this regard is inadmissible. Dr. Laughery will not be permitted to opine or otherwise offer testimony to question what a fact witness did or did not see, did or did not know, did or did not understand, or did or did not do at a given point in time. Nor may he take issue with the credibility or accuracy of the testimony of a fact witness in this case.

Given the fact that human factors engineering has played a role in the development of the PCA 3 and each side seeks to introduce expert testimony in the field of human factors engineering, the court will allow its admission appropriately cabined in a manner to assist the jury. Accordingly, the motion in limine regarding Dr. Laughery (Dkt. No. 71) is **GRANTED in part** and **DENIED in part**.

C. Defendants' Motion for Summary Judgment (Dkt. No. 69).

Defendants move for summary judgment on the following grounds: (1) the warnings accompanying the PCA 3 are adequate as a matter of law; (2) learned intermediaries were aware of the dangers of misprogramming the concentration in the PCA 3; (3) the misprogramming of the concentration was an open and obvious danger; (4) Plaintiffs have failed to produce evidence that an inadequate warning proximately caused Williamson's death; (5) MRH's failure to adequately monitor Williamson was the intervening and superseding cause of his death; and (6) Plaintiffs have failed to produce evidence of an express warranty. Because there are genuine issues of material fact concerning each of these issues, summary judgment will be denied.

1.

Pursuant to Federal Rule of Civil Procedure 56(a), the court must "grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Glynn v. EDO Corp., 710 F.3d 209, 213 (4th Cir. 2013). When making this determination, the court should consider "the pleadings, depositions, answers to interrogatories, and admissions on file, together with . . . [any] affidavits" filed by the parties. Celotex, 477 U.S. at 322. Whether a fact is material depends on the relevant substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." Id. (citation omitted). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. If that burden has been met, the non-moving party must then come forward and establish the specific material facts in dispute to survive summary judgment. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986).

In determining whether a genuine issue of material fact exists, the court views the facts and draws all reasonable inferences in the light most favorable to the non-moving party. Glynn, 710 F.3d at 213 (citing Bonds v. Leavitt, 629 F.3d 369, 380 (4th Cir. 2011)). Indeed, "[i]t is an 'axiom that in ruling on a motion for summary judgment, the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in [her] favor.'" McAirlaids, Inc. v. Kimberly-Clark Corp., No. 13-2044, 2014 WL 2871492, at *1 (4th Cir. June 25, 2014) (internal alteration omitted) (citing Tolan v. Cotton, 134 S.Ct. 1861, 1863 (2014) (per curiam)). Moreover, "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ." Anderson, 477 U.S. at 255. However, the non-

moving party "must set forth specific facts that go beyond the 'mere existence of a scintilla of evidence.'" Glynn, 710 F.3d at 213 (quoting Anderson, 477 U.S. at 252). Instead, the non-moving party must show that "there is sufficient evidence favoring the non[-]moving party for a jury to return a verdict for that party." Res. Bankshares Corp. v. St. Paul Mercury Ins. Co., 407 F.3d 631, 635 (4th Cir. 2005) (quoting Anderson, 477 U.S. at 249). "In other words, to grant summary judgment the Court must determine that no reasonable jury could find for the non[-]moving party on the evidence before it." Moss v. Parks Corp., 985 F.2d 736, 738 (4th Cir. 1993) (citing Perini Corp. v. Perini Const., Inc., 915 F.2d 121, 124 (4th Cir. 1990)).

2.

Summary judgment fails in this case for a number of reasons. First, drawing all reasonable inferences in the light most favorable to Plaintiffs, there are disputes over multiple facts that could affect the outcome of this case. For example, it is clear to the court that reasonable minds could differ as to whether the instructions and labels on the PCA 3 were adequate, particularly given the screen stating "CONFIRM CONCENTRATION TO PHYSICIAN RX." Additionally, based on the differing testimony of the MRH nurses, a dispute exists as to whether the nurses were actually aware of the potential dangers of misprogramming the drug concentration in the PCA 3, or whether the danger was open and obvious. See Caldwell Dep., Dkt. No. 70-3, at 48:10-49:4; Via Dep., Dkt. No. 93-12, at 71:25-72:5. There is also a factual question as to whether the MRH staff failed to adequately monitor Williamson and, if so, whether that failure was an intervening and superseding cause of his death.

Defendants further argue that they are entitled to summary judgment because Plaintiffs cannot prove their case without expert testimony showing the inadequate instructions and warnings associated with the PCA 3 were the proximate cause of Williamson's death. Because this is a medical device case, Defendants claim "'proof of legal causation . . . must be by expert testimony

and the expert's opinion must be stated in terms of reasonable probability."' Defs.' Mot. Summ. J., Dkt. No. 70, at *17 (emphasis omitted) (quoting Hartwell v. Danek Medical Inc., 47 F. Supp. 2d 703, 707 (W.D. Va. 1999)).

To be sure, the court has limited the testimony of Drs. Laughery and Collins. But these rulings are not dispositive of the entirety of Plaintiffs' case. Plaintiffs will present evidence as to the cause of Williamson's death from Robert C. Murrell, M.D. and Jonathan L. Arden, M.D. These doctors are expected to testify based on the facts of this case and their expertise as to the amount of Dilaudid received by Williamson and the effect of that drug on him. Dr. Collins may offer expert opinions regarding medication safety in a hospital setting, the dosage of Dilaudid received by Williamson, the programming of the PCA 3 pump and the adequacy of the instructions and warnings thereon. Employing principles of human factors engineering, Dr. Laughery may testify as to the adequacy of the instructions and warnings associated with the PCA 3 pump. Certainly, these issues will be contested by Defendants. However, it appears at this stage that there is sufficient testimony, including expert testimony, as to causation to create a genuine issue of material fact precluding entry of summary judgment.

Finally, Defendants seek summary judgment on Count III of the Amended Complaint alleging breach of express warranty. Defendants argue that there were no express warranties made by the manufacturer of the PCA 3 that the machine would prevent misprogramming errors altogether, and there is no evidence in the record that such a warranty formed the basis of the bargain between the seller and purchaser of the PCA 3.

Express warranties are "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods" and "[a]ny description of the good" that forms the "basis of the bargain" between the buyer and seller that the goods will conform to the affirmation, promise, or description. Va. Code Ann. § 8.2-313. While the creation of an express warranty does not require

the use of any magic words, there must be "at least *some* affirmative statement or promise regarding the condition of the item sold . . . by the product's manufacturer or seller." Richard v. Wal-Mart Stores, Inc., No. CIV. A. 96-0011-C, 1997 WL 578710, at *7 (W.D. Va. Aug. 25, 1997). The buyer need not rely on the seller's description of the goods, but the description must be more than "the seller's mere opinion." Martin v. Am. Med. Sys., Inc., 116 F.3d 102, 105 (4th Cir. 1997) (citing Daughtrey v. Ashe, 243 Va. 73, 413 S.E. 2d 336 (1992)). The "inquiry focuses on what it is that the seller agreed to sell" and whether the parties intended for "their bargain to include the seller's description of the goods . . . ." Id. Thus, "whether a particular affirmation of fact made by the seller constitutes an express warranty is generally a question of fact." Bayliner Marine Corp. v. Crow, 257 Va. 121, 127, 509 S.E.2d 499, 502 (1999).

Exhibits U and V to Plaintiffs' Opposition to Defendants' Motion for Summary Judgment are sufficient at this stage to defeat summary judgment on the express warranty claim. Exhibit U is a news release from Abbott Laboratories regarding the PCA 3. Dkt. No. 93-18 at *3. That release discusses the new features of the PCA 3, including:

> A built-in bar code reader – one that works in concert with bar-code labeled Abbott prefilled vials that snap into the pump – makes PCA3 the first PCA pump to incorporate this integrated safety feature. The second significant advancement is that the PCA3 identifies drug name and concentration within the vial and automatically inputs the information into the pump program. These two "firsts" should help address many preventable errors as less manual programming is required.
>
> . . . .
>
> "When used with Abbott bar-coded syringes, the PCA3 becomes the first pump to fully integrate bar coding into the device. No other PCA pump has that feature."

Id. at *2 (emphasis added). Exhibit V appears to be a PCA 3 brochure. It states:

> Designed specifically to help prevent medication errors that commonly arise in patient-controlled analgesia, the LifeCare PCA pump features an integrated bar code reader and other features to enhance safe delivery.

. . . .

Integrated bar code reader confirms drug and concentration

Pre-filled, bar –coded medication vials with colored labels or custom-filled vials with pharmacy-generated bar codes

Confirmation screens to add an extra level of safety

Dkt. No. 93-19. Whether these statements were part of the basis of the bargain creating an express warranty is a question for the jury. As such, the court cannot decide the express warranty claim at this stage.

In sum, Defendants' motion for summary judgment must be denied.

III.

For these reasons, Defendants' motions in limine concerning Dr. Laughery (Dkt. No. 71) and Dr. Collins (Dkt. No. 73) are **GRANTED in part** and **DENIED in part**; Defendants' objection to the report and recommendation concerning Dr. Arden (Dkt. No. 67) is **OVERRULED**, the report (Dkt. No. 60) is **ADOPTED** in its entirety and Defendants' motion to exclude Dr. Arden (Dkt. No. 49) is **DENIED**; and Defendants' motion for summary judgment (Dkt. No. 69) is **DENIED**.

An appropriate Order will be entered.

Entered: December 19, 2014

Michael F. Urbanski

Michael F. Urbanski
United States District Judge